REMARKS

Favorable consideration and allowance are respectfully requested for claims 1-16 in view of the foregoing amendments and the following remarks.

The rejections of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, first paragraph, in paragraphs 7 and 8 of the Office Action, as allegedly lacking adequate written description, are respectfully traversed.

The language in claim 1 that was identified as new matter is removed from the claim by this amendment. As such, the claim now reads, in relevant part, "or a protein encoded by a polynucleotide comprising SEQ ID NO: 1, 3, 5, 7, 9, 11 or 13 or a polynucleotide which is at least 90% homologous thereto, or antisense polynucleotides thereof,".

The phrase "ionic mileu" is also removed from claim 1.

Accordingly, the written description rejections in paragraphs 7 and 8 of the recent Office Action are believed to be addressed and withdrawal of these rejections is respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, first paragraph, as allegedly lacking enablement for a method for detecting a pain-regulating substance is respectfully traversed.

As amended, claim 1 is directed to "A method for detecting a candidate substance". Claim 1 is also amended to recite "pain-relevant" in step C. New claim 33 depends from claim 1 and adds that the step of determining whether the test substance is a pain-relevant substance involves testing the test substance for pain relevance in an animal model. Because claim 1 is now directed to detecting candidate substances, there can be no requirement that one practicing the claimed invention is guaranteed to successfully identify a pain-regulating substance.

A person of skill in the art could readily envision or even obtain a protein or polynucleotide which is 90% homologous to those recited in the specification or a part protein which is at least 10 amino acids long. Further, the functional parameters modified by the binding of the test substance are particularly identified in the claim. The experiment to measure the functional parameter is

actually an affirmative step of certain embodiments of the claimed invention, rather than an experiment which should be considered for purposes of "unde experimentation" under the enablement requirement. The tests required to measure the listed functional parameters are all within the skillset of one of skill in the art. This is particularly so, given the high level of skill in the art of screening for pharmaceutical compounds. Given this high level of skill, one of skill in the art would be able to practice the full scope of the claims without undue experimentation.

Thus, a person of skill in the art would be able to practice the claimed invention without further undue experimentation. Accordingly, reconsideration and withdrawal of the rejection of claims under 35 U.S.C. § 112, first paragraph, are respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, first paragraph, in paragraph 10 of the Office Action, as allegedly lacking adequate written description, is respectfully traversed.

Claim 1 is clear that measuring the functional parameter involves measuring the regulation, inhibition or activation of receptors, ion channels or enzymes or via measurement of a modification in gene expression, ionic milieu, pH or membrane potential, or via a modification in enzyme activity or concentration of a second messenger. As such, the claim is directed to a discrete list of functional parameters that may be measured. A person of skill in the art could measure these functional parameters using tests which are generally known to those of skill in the art. A patent specification is not required to recite that which is already known.

The genus of part proteins which are at least 10 amino acids long is adequately described by the present specification, which recites the full length protein. This genus of part proteins includes only those proteins sharing the sequence of one of the other listed proteins in the claim. Accordingly, the protein is described by its physical amino structure, which is a distinguishing identifying characteristic that may be used to differentiate the genus from other proteins.

Accordingly, reconsideration and withdrawal of this rejection in paragraph 10 of the recent Office Action is respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, second paragraph, as indefinite, is respectfully traversed.

The Office Action indicates that "it is not clear what constitutes '***a potential*** regulating influence'." The claim does not recite the objected-to phrase. Further, as indicated above, the claim is amended to recite that it is directed to a method for detecting a candidate substance rather than a method for detecting a pain-regulating substance. Because the claim is directed to detecting a candidate substance, the claim should not be read to require that pain-regulating substance will actually be identified and the question of whether a potential regulating influence means a substance will, or will not be a pain-regulating substance is not at issue.

Accordingly, reconsideration and withdrawal of this rejection in paragraph 11 of the recent Office Action are respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, second paragraph, for omitting essential steps, is respectfully traversed.

As indicated above, claim 1 recites to a method for detecting a candidate substance rather than a method for detecting a pain-regulating substance. The claims recite a complete series of steps that allow one of skill in the art to achieve the goal of detecting candidate compounds. As such, the claims do not lack essential steps and reconsideration and withdrawal of this rejection in paragraph 12 of the recent Office Action are respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, second paragraph, in paragraph 13 of the recent Office Action, is respectfully traversed.

Claim 1 is amended to clarify that in step (b), the test substance may bind the protein or part protein or the protein or part protein synthesized by the cell. Step (a) recites that the test substance may be incubated with a protein, a part protein, or a cell or a preparation from a cell which has synthesized at least one of these proteins or part proteins. Step (b) recites that, in addition to measuring the binding of the test substance to the protein or part protein or the protein or

part protein synthesized by the cell, a functional parameter may be measured, this functional parameter relates to the cell or preparation from the cell.

As such, a person of skill in the art would recognize the relationship of steps (a) and (b) of amended claim 1. Reconsideration and withdrawal of this rejection in paragraph 13 of the recent Office Action are respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, second paragraph, in paragraph 14 of the recent Office Action, is respectfully traversed.

Claim 1 specifically identifies the factors which may be measured as functional parameters. As indicated above, the term "ionic milieu" has been removed from the claim. The claim is directed to a process where after the incubating step, the relevant functional parameter is measured. If there is an observable change in the measured parameter after the incubation, this would indicate that the test substance had an effect on the parameter. In this way, the claimed method provides one of skill in the art with useful information for detecting candidate substances. Accordingly, reconsideration and withdrawal of this rejection in paragraph 14 of the recent Office Action are respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15, in paragraph 15 of the recent Office Action, is respectfully traversed.

This appears to be an indefiniteness rejection. The Office Action rejects the claims because there are allegedly two possibilities for the final step of the claim. Even assuming there were two possibilities, this would not render the claim indefinite, as the scope of the claims is still apparent to one of skill in the art. In this case, the claims are not "insolubly ambiguous." Moreover, given the amendment to claim 1 so that it is directed to a method for detecting a candidate substance rather than a method for detecting a pain-regulating substance, one need not conclude that a substance is pain regulating to practice the claimed invention. As such, reconsideration and withdrawal of the rejection in paragraph 15 of the recent Office Action are respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, second paragraph, in paragraph 16 of the recent Office Action, is respectfully traversed.

The Office Action asserts that it is not evident how this limitation of claim 4 relates to the claimed method. The claims show how the limitation relates to the claimed method. In particular, claim 3 states that the manipulation by genetic engineering allows the measurement of at least one functional parameter. Claim 4 depends from claim 3 and indicates that the manipulation by genetic engineering causes expression of a G protein (GTP-binding protein) or introduction of a reporter gene. As explained in paragraph [0019] of the specification, this modification contemplates, for instance, the introduction of a chimeric G protein which allows a modification of a signal path or introduction of a promiscuous G protein which binds very readily.

A person of skill in the art could readily determine the scope of claim 4, and accordingly it meets the requirements for definiteness. Reconsideration and withdrawal of the rejection are respectfully requested.

The rejection of claims 1-4, 7-12 and 14-15 under 35 U.S.C. § 112, second paragraph, in paragraph 17 of the recent Office Action, is respectfully traversed.

The objected to phrase has been removed from the claim and this rejection is therefore rendered moot. Reconsideration and withdrawal of the rejection in paragraph 17 of the recent Office Action are respectfully requested

The rejection of claims 1, 10-12 and 14 under 35 U.S.C. § 102 as anticipated by Jensen et al. (1992) is respectfully traversed.

Step (b) of claim 1 recites either measuring the binding of the test substance or measuring one of several listed functional parameters, including the regulation, inhibition or activation of receptors. Jensen describes administering glutamate and testing for a pain response. The Office Action asserts that measuring the glutamate concentration injected or the subsequent behavior amounts to measuring a functional parameter. This assertion, however, ignores the language in the claim which defines the functional parameters to be measured. The functional parameters contemplated in the claim do not include the amount of the test substance administered or the physical behavior of a test subject.

In the experiment associated with Figure 4, Jensen administers MK 801 and then glutamate and observes no pain response. This does not amount to the claimed method of measuring the regulation, inhibition or activation of a receptor. Instead, Jensen merely teaches blocking the glutamate receptor and then noting that subsequent administration of glutamate elicits no pain response in the test animals.

Further, Jensen does not make clear that the glutamate was administered to one of the proteins, cells or cell preparations recited in step (a) of claim 1 and then that step (b) was perfomed. Jensen states that administration of glutamate to a variety of brainstem sites elicits no pain response (see the left-hand column on page 542). The Office Action offers Li as teaching that Vglut1 is present in the medulla. In the experiments where the glutamate receptor was blocked, glutamate was only administered to certain positions in the brain, not the breadth of the brain sites described in Figures 1 and 2 of Jensen.

Accordingly, Jensen does not teach each and every limitation of the presently claimed invention and reconsideration and withdrawal of this rejection are respectfully requested.

If there are any questions regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

If necessary to effect a timely response, this paper should be considered as a petition for an Extension of Time sufficient to effect a timely response, and please charge any deficiency in fees or credit any overpayments to Deposit Account No. 05-1323 (Docket No. 029310.52995US).

Respectfully submitted,

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